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REPORT DATE: Ø^à!~ æ^ ÁÖFG

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) 01-02-2012		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 1 FEB 2011 - 31 Jan 2012	
4. TITLE AND SUBTITLE Post Admission Cognitive Therapy (PACT) for the Inpatient Treatment of Military Personnel with Suicidal Behaviors: A Multi-Site Randomized Controlled Trial				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-11-2-0106	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr. Marjan Holloway E-Mail: mholloway@usuhs.mil				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Henry M. Jackson Foundation for the Advancement of Military Medicine Rockville, MD 20852				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The broad objective of the proposed study is to empirically evaluate the efficacy of a cognitive behavioral intervention, titled, Post Admission Cognitive Therapy (PACT), for military personnel psychiatrically hospitalized due to a suicide-related event with either a recent or a lifetime suicide attempt. The primary outcomes will be incidence of repeat suicide attempt(s) and number of days until a repeat suicide attempt. Secondary outcomes include psychiatric symptoms, repeat number of psychiatric hospitalization(s), hope for one's future, and acceptability of treatment. A multi-site, single-blind, randomized controlled trial will be the research design. A total of 218 individuals will be recruited from the inpatient psychiatric and traumatic brain injury (TBI) units at the Walter Reed National Military Medical Center and Fort Belvoir Community Hospital. Participants will be randomized into one of two conditions: (1) PACT + Enhanced Usual Care (EUC) or (2) EUC. The PACT+EUC condition will consist of six 60-90 minute individual cognitive behavioral therapy sessions administered over preferably three days during the inpatient stay and up to four telephone booster sessions. The EUC condition will consist of usual psychiatric care patients receive during their hospitalization, the assessment services provided by MA and/or PhD level clinicians, and case management services provided for one year by Bachelor's level research personnel. Follow-up assessments will be conducted at 1, 3, 6, and 12-month post discharge by blind PhD level clinicians.					
15. SUBJECT TERMS Suicide Prevention, Acute Care, Inpatient Treatment, Cognitive Behavior Therapy					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	27	19b. TELEPHONE NUMBER (include area code)

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Introduction

Background: Suicide remains a serious national public health problem and has become a leading cause of death in the United States military. To date, there is no evidence-based civilian or military inpatient interventions aimed at the reduction of suicide behavior. Our proposal addresses this important gap and aims to evaluate an innovative suicide intervention, *Post Admission Cognitive Therapy* (PACT). Left untreated, severe suicide ideation and/or suicide attempts that require psychiatric hospitalization may place an individual at a lifetime risk for increased psychopathology, subsequent suicide behavior, and death.

Objective: The broad objective is to implement and empirically evaluate the efficacy of a cognitive behavioral intervention program, titled, *Post Admission Cognitive Therapy* (PACT), for military service members and beneficiaries admitted for inpatient care due to severe suicide ideation and/or a recent suicide attempt.

Specific Aims: To evaluate the efficacy of PACT plus Enhanced Usual Care (EUC) versus EUC for the prevention of suicide in psychiatrically hospitalized military personnel and beneficiaries at follow-up (1, 3, 6, and 12-month) on (1) incidence of repeat suicide attempt(s) and number of days until a repeat suicide attempt (primary outcomes), and (2) psychiatric symptoms (depression, trauma, sleep, suicide ideation), repeat number of psychiatric hospitalization(s), hope for one's future, and acceptability of treatment (as measured by time to linkage to specialty care, attitudes toward seeking help for mental health issues, and subsequent mental health service utilization) (secondary outcomes). We expect that adults in the PACT+EUC (experimental) condition compared to those in the EUC (control) condition will show favorable outcomes on both primary and secondary measures.

Study Design: The research design is a multi-site, single-blind, randomized controlled trial (RCT). A total of 218 individuals who are over the age of 18, able to communicate in English and willing to provide informed consent will be recruited from the inpatient psychiatric units at the Walter Reed Army Medical Center and the Naval Medical Center Portsmouth. Participants will be randomized into one of two conditions: (1) [Post Admission Cognitive Therapy (PACT) + Enhanced Usual Care (EUC)] or (2) Enhanced Usual Care (EUC). Individuals randomized into PACT+EUC will participate in the study assessments, receive six 60-90 minute individual face-to-face PACT psychotherapy sessions provided during their inpatient stay, up to a maximum of four 60-minute phone PACT booster sessions during the 3 months post hospital discharge, and case management services for 12 months. Individuals randomized into the control condition (EUC) will not receive the study intervention; they will receive the usual care provided in the inpatient setting, participate in study assessments, and receive case management services for 12 months. Patients in both conditions will be assessed on the dependent measures at baseline and at 1-, 3-, 6-, and 12-month follow-up intervals.

Relevance: Delivering a brief and possibly potent psychotherapeutic intervention during a psychiatric inpatient hospitalization followed by an aftercare component aims to directly target individuals at high risk for future suicide behavior, specifically young, psychiatrically hospitalized adults under the direct stress of a military career. The development and empirical validation of an inpatient cognitive behavioral treatment is a significant endeavor in our national as well as Department of Defense (DoD) suicide prevention efforts. If *Post Admission Cognitive Therapy* is found to be efficacious, the intervention can be subsequently disseminated to inpatient settings as the standard of care for military personnel and beneficiaries admitted for suicide-related events.

Body

Quarter 1: Funding notification was received from USAMRMC on January 31, 2011. Much of the first quarter was spent on the following three tasks: (1) working directly with the Henry Jackson Foundation to process the subawards for the study (Denver VA; Duke University; KAI, Inc.; University of Michigan; and University of Pennsylvania) ; (2) working directly with the regulatory boards at the Uniformed Services University of the Health Sciences, the Walter Reed Military Medical Center (WRAMC – before the Base Realignment and Closure [BRAC]), the National Naval Medical Center (NNMC), the Navy Medical Center Portsmouth (NMCP), and the Human Research Protections Office (HRPO) at the USAMRMC Office of Research Protections to prepare all required IRB-related documentation; and (3) advertising, interviewing, and selecting candidates for hiring. An additional endeavor included the development of a study standard operating procedural manual which covers topics such as recruitment, consenting, and assessment. Multiple conference calls were organized between the study Principal Investigator and various collaborators involved in the implementation of this study to move forward on the setup for the study infrastructure.

Quarter 2: Much of the second quarter was spent on the following three tasks: (1) working directly with the Henry Jackson Foundation to continue on the processing of the sub-awards for the study (Denver VA; Duke University; KAI, Inc.; University of Michigan; and University of Pennsylvania); (2) working directly with the regulatory boards at the Uniformed Services University of the Health Sciences, the Walter Reed Army Medical Center (WRAMC), the National Naval Medical Center (NNMC), the Navy Medical Center Portsmouth (NMCP), and the Human Research Protections Office (HRPO) at the USAMRMC Office of Research Protections to prepare all required IRB-related documentation; and (3) advertising, interviewing, and selecting candidates for hiring. The PI met weekly with all Clinical Trials staff in the laboratory to discuss issues pertaining to the management of all psychotherapy trials. The sessions were used effectively to problem solve obstacles and implementation related issues.

During the course of the second quarter, unfortunately, we were informed of the sudden death of Dr. Thomas TenHave at the University of Pennsylvania who was listed on the original grant application as a consultant biostatistician. We have arranged for KAI and our biostatistician at USUHS to assist with the study-related analyses. If additional statistical guidance is required for more complex analyses, we will look for an individual with expertise in clinical trials methodology and statistical procedures.

Within this quarter, we also encountered a number of challenges associated with the BRAC. For instance, there was a great deal of confusion and unclear instruction about how the WRAMC and NNMC IRBs would be handling new protocols. We had initially set out to obtain impact statements from WRAMC Departments of Psychiatry, Medical Records, and Information Management only to find out later that the same documents needed to be obtained from NNMC because the WRAMC signed documents are not acceptable by NNMC. The WRAMC and the NNMC IRBs did not have a clear and systematic plan of action for the merge and upon setting up a conference call, we realized that our conversation was actually serving as a method of communication among the parties to best determine how new protocols, in general, should be handled by them. We understand that the BRAC transition placed a great deal of pressure on the

various individuals within the system. We worked with all involved parties to move the project forward in an efficient manner.

An additional endeavor was to develop a study standard operating procedural manual which covers topics such as recruitment, consenting, and assessment. We began work on a draft of the PACT treatment manual and a session by session guide for the study therapists. Multiple conference calls have taken place between the study Principal Investigator and various collaborators involved in the implementation of this study to move forward on the setup for the study infrastructure. Training materials for the assessment protocol have been prepared.

Quarter 3: During the third quarter, we engaged in the following activities: (1) working directly with the Henry Jackson Foundation to ensure the timely processing of the sub-awards and contracts for the study (Denver VA; Duke University; KAI, Inc.; University of Michigan; and University of Pennsylvania); (2) working directly with the regulatory boards at the Uniformed Services University of the Health Sciences, the Walter Reed National Military Medical Center (WRNMMC), the Navy Medical Center Portsmouth (NMCP), and the Human Research Protections Office (HRPO) at the USAMRMC Office of Research Protections to prepare all required IRB-related documentation; (3) continuing the process of new employee selection and recruitment; (4) providing training to newly hired staff; (5) coordinating with various study collaborators; (6) purchasing study-related materials and supplies; (7) refining study-related assessment, standard operating procedures, and treatment protocols, and (8) working with the KAI team to problem solve study-related challenges and plan for the multi-site RCT.

During the weekly “Clinical Trial Management Meetings”, the PI met with the research staff at USUHS to discuss issues pertaining to the daily execution and management of study related activities. Meeting sessions were used to problem solve research-related obstacles and implementation related issues. In addition, weekly “PACT Treatment Meetings” were held with doctoral level clinicians to discuss active patient cases on the PACT pilot studies (currently underway) which also involves listening to digital recordings of therapy sessions and/or reviewing of typed transcribed sessions for the purposes of treatment refinement and integrity. The PI also met periodically with the KAI staff as well as maintained phone and email communication with off-site collaborators to update them of the progress being made with the regulatory board/IRB phase of the project.

Moreover, we continued with the advertising, interviewing, and hiring of study-related staff. We began looking for a replacement after the unexpected passing of Dr. Thomas TenHave – a consultant biostatistician from the University of Pennsylvania named on the grant application. A decision was made to hire a Master’s level data management and biostatistics staff member at a 40% effort on the project to provide on-site assistance at USUHS. Given that no study data has been collected to date, we do not expect requiring advanced biostatistics support until Years 4 and 5 of the study. We will continue to consider suitable candidates to assist us with complex analytic procedures upon the completion of the study.

The most challenging aspect of overseeing this study was related to the Base Realignment and Closure. In fact, we encountered a number of challenges associated with the transition. For instance, there was a great deal of confusion and unclear instruction about how the newly formed WRNMMC IRB would be handling new protocols. As a result, we scheduled meetings with both

the USUHS and WRNMMC IRB leadership to address the best approach in moving forward. However, regardless of our continued proactive efforts, we encountered situations that clearly wasted our staff time and study resources due to BRAC related transitional issues. For instance, the Cooperative Research and Development Agreement (CRADA) is one document that is needed to setup a financial relationship between HJF and WRNMMC. This document, in our past experience, has taken at least 4-6 months to get processed and approved. Therefore, given our past experiences, we had requested to get this document processed soon after our funding had been obtained from USAMRMC. Unfortunately, to date, no movement has been made on this front. During our most recent meeting with the WRNMMC leadership, we were told that the CRADA processing had come to a stop because they were planning to implement new procedures. To date, we do not have a clear understanding of these new procedures and continue to work with the IRB designated staff at WRNMMC to get this issue resolved.

Additional BRAC related issues that have come up are related to the credentialing of study assessors and therapists at the WRNMMC inpatient psychiatric unit. After the BRAC, it became clear that there was not a standard operating procedure yet in place to credential new therapists that were not yet licensed, working under direct supervision of a licensed Psychologist. Much time and effort was devoted to working closely with the WRNMMC Department of Psychiatry and Credentialing Office, through phone calls, emails, and face to face meetings, to formulate a plan that would satisfy the WRNMMC medical standards for unlicensed clinicians (e.g., postdoctoral fellows) providing treatment. After submitting the necessary paperwork, all study therapists (hired to date) have now been approved to provide services at WRNMMC. BRAC has also resulted in a new parking policy at USUHS which requires all HJF employees to use either public transportation or park at an off-site location. Given that many of our staff members were hired prior to the implementation of this strict policy, we had to problem solve scheduling issues and individual employee concerns about the impact of this new policy on their position.

In summary, the BRAC transition resulted in a need for us to basically “start over” again – meaning that all the infrastructure setup previously at the Walter Reed Army Medical Center as a foundation for our work on this study was for the most part lost. There are new staff, new offices, and new policies at the WRNMMC which means that we are spending a great deal of our time setting up the infrastructure needed for this research. This, of course, was not expected at the time of the writing of the funded grant application and not taken into account in terms of our study timeline. For example, we have had to start with a new system for VPN (Virtual Private Network) and Essentris (i.e., inpatient electronic medical record) access. We have had to alter our plans for the requesting of department approvals on Impact Statement documents required by the WRNMMC IRB. Having said all this, we are hopeful that in the year to come, we can continue to problem solve challenges as they arise to ensure that our study objectives are met within a reasonable and timely manner.

Quarter 4: During the past quarter, we made the submission of the Master Protocol and accompanying documents to the WRNMMC IRB. We advertised, reviewed applications, and hired qualified study personnel as needed. We continued to train qualified study personnel on the study’s standard operating procedures, the conduct of study assessments, and delivery of the treatment protocol. We participated in regular conference calls with the Denver VA PI (Dr. Lisa Brenner) and collaborated on the creation of a focused assessment and treatment considerations guide for clinical work with suicidal individuals with traumatic brain injury. We participated in

regular conference calls with the Duke University PI (Dr. David Goldston) in order to finalize study baseline and follow-up assessment procedures, to make plans to shorten the assessment protocol to ease burden on the participants, and to discuss strategies for the retention of study participants over the 12-month follow-up period. We participate in conference calls with the University of Michigan PI (Dr. Cheryl King) to begin planning for the post-discharge booster sessions and related assessment for this component of the intervention. We participated in regular conference calls or in-person meetings with the KAI team to setup study secure website and study related forms. Furthermore, a sustained effort was made to refine and revise the PACT treatment manual and rating scale based on the current work being conducted on the pilot trials. We began to develop a case management procedural guide. We contacted the Chief of Inpatient Psychiatry at FBCH to arrange a visit to Ft. Belvoir to meet with the inpatient psychiatry staff, get a tour of the facilities, and to problem solve implementation obstacles. We prepared and submitted the Year 1 annual report to USAMRMC.

A brief summary of the progress made on all Year 1 tasks listed on the original Statement of Work is provided below.

Overview of Study Activities for Quarters (Q) 1-4

Performance Period: February 1, 2011 to January 31, 2012

1. Scheduled regular conference calls for key study collaborators (Q 1-4)

The PI maintained regular face-to-face, email, and/or phone communication with key study collaborators, primarily to establish the infrastructure for our planned research. Bi-weekly conference calls were held beginning in December, 2011 with Dr. David Goldston, the PI at Duke University to discuss ongoing IRB related issues. We coordinated efforts to generate a master protocol for the study given Duke University's planned involvement in conducting the phone follow-up assessments. Dr. Goldston reviewed and approved the "Site-Specific Addendum" to the IRB application that outlines Duke University's role in the study. The study PI and Dr. Goldston also finalized study baseline and follow-up assessment procedures, made plans to shorten the assessment protocol to ease burden on the participants, and discussed strategies for the retention of study participants over the 12-month follow-up period.

A conference call was held on January 5, 2012 with Lisa Brenner, Ph.D. to collaborate on the creation of a focused assessment and treatment considerations guide for clinical work with suicidal individuals with traumatic brain injury (TBI). Two training sessions were scheduled for February 8th and February 15th, 2012. Furthermore, conference calls were scheduled with Cheryl King, Ph.D. to update her on the progress of the study and to discuss ongoing IRB related issues. We will plan for the post-discharge booster sessions and related assessment for this component of the intervention. The study PI participated in regular conference calls or in-person meetings with the KAI team to setup study secure website and study related forms.

Summary of Communication among Principal Investigator (PI) and other Key Study Collaborators

Lt Col Geoffrey Grammer, Chief of Inpatient Psychiatry at WRNMMC, reviewed and approved an Impact Statement as required by the WRNMMC IRB. Ongoing communication with Dr.

Grammer was maintained regarding patient recruitment and how best to implement the pilot trials which will inform this project.

The study PI approached Dr. Jennifer Weaver, Chief of Inpatient Psychiatry at Ft. Belvoir, to discuss the feasibility of recruiting study participants from that site. Dr. Weaver was previously involved with our pilot trials performed at WRAMC and has been very eager and excited to have our research team become involved in the new unit at Ft Belvoir. We are currently working on a letter of support to be provided to us from this site and have requested an Impact Statement as well. We plan to arrange a visit to Ft. Belvoir to meet with the inpatient psychiatry staff, get a tour of the facilities, and to problem solve implementation obstacles. We have been asked to delay this visit until the recent accreditation visit comes to an end.

2. Submitted appropriate IRB applications for Site 1 (WRNMMC) study implementation (Q 1-2); Did not submit appropriate IRB applications for Site 2 (NMCP) study implementation (Q 1-4) – Instead, added Ft. Belvoir Community Hospital

Preparation of IRB Documents for WRNMMC and Affiliated Academic Sites

Communication with the WRNMMC Department of Clinical Investigations involved clarification on issues related to which regulatory board would serve as IRB of record, what types of procedural changes would need to be considered given the Base Realignment and Closure (BRAC), and which IRB would defer to another one's decision.

To ensure that we are following the correct WRNMMC procedures for the submission of the new protocol and to maximize the collaboration/communication among the various IRBs involved, we requested to setup several meetings with the WRNMMC and USUHS leadership. Over the past year, we had several face-to-face and conference call meetings with Ms. Denise Neath, WRNMMC IRB coordinator, and Ms. Maggie Pickerel, USUHS IRB Director. We also have consulted regularly with Ms. Sheila Gaines (IRB Coordinator, NNMC), Ms. Julie Lee (Regulatory Specialist, HJF), Ms. Karen Eaton (HRPO), and Dr. Richard Levine (Assistant Vice President of Research). The purpose of these meetings was to establish the most efficient IRB review process and to maximize the collaboration and communication among the various IRBs involved.

A meeting held on October 20, 2011, between the study PI, USUHS research staff, the USUHS IRB director, and the WRNMMC IRB director and administrative staff, discussed the details of study design and the best plan of action for ensuring a timely review and approval of the study protocol. First, Ms. Maggie Pickerel reported that the Naval Medical Center Portsmouth (NMCP) has not agreed to defer to the USUHS IRB or to the WRNMMC IRB, thus requiring an independent review by their full IRB committee. Ms. Sheila Gaines, one of the WRNMMC IRB administrators (who previously worked at the NMCP IRB) was designated the task of contacting the NMCP IRB to present an argument for why they should defer to the WRNMMC IRB. We discussed the advantages of considering Ft. Belvoir as a recruitment site given that the WRNMMC IRB approval will provide coverage for that site. Then at the very least, we can avoid lengthy delays due to the NMCP IRB involvement and begin study recruitment at the two local sites (i.e., WRNMMC and Ft Belvoir) upon WRNMMC/USUHS/HRPO approvals without the need to wait for the NMCP IRB. If recruitment goals are not being adequately met, we can

then re-engage with NMCP and submit an application to their IRB at a later time. Second, we discussed the new WRNMMC IRB procedures for the submission of a new protocol and addressed issues that had remained unresolved due to the BRAC transition. The group decision was that the following procedure will be used to gain all regulatory approvals for this study:

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| Step 1. | Submit Master Protocol & Supporting Documents to the WRNMMC IRB |
| Step 2. | Submit Master Protocol & Supporting Documents to HRPO for Preliminary Review ONLY |
| Step 3. | Obtain WRNMMC IRB Approval |
| Step 4.a. | Submit WRNMMC IRB Approved Master Protocol & Supporting Documents to the USUHS IRB |
| Step 4.b. | Submit WRNMMC IRB Approved Master Protocol & Supporting Documents + Site Specific Addendums to the Duke U, U of Michigan, and Denver VA IRBs |
| Step 4.c. | Submit WRNMMC IRB Approved Master Protocol & Supporting Documents to HRPO |
| Step 5. | Obtain Secondary Concurrence from the USUHS IRB (i.e., USUHS IRB will defer to the WRNMMC IRB) |
| Step 6. | Obtain IRB Approvals for the Duke U, U of Michigan, and Denver VA IRBs |
| Step 7. | Submit the Approved Denver VA IRB Protocol to the Chesapeake IRB for Secondary Review |
| Step 8. | Obtain Approval from the Chesapeake IRB |
| Step 9. | Obtain Approval from HRPO |
| Step 10. | Begin with Study Recruitment |

Given the recommendation provided by WRNMMC IRB staff, the submission of the protocol was postponed until the 4th quarter. The PI and key study personnel completed and submitted the following required IRB documents to the WRNMMC IRB (Step 1.):

- Human Subjects Master Protocol
- Site Specific Addendum for Duke University
- Consent Form and HIPPA Authorization Forms
- List of 20 Appendices to Support IRB Application

Upon obtaining WRNMMC IRB approval, we will continue the process with the remaining steps to move the project forward.

3. Interviewed, selected, and hired qualified study personnel for both implementation sites (Q 1-2)

The PI gained approval from Henry M. Jackson Foundation to advertise for several positions, reviewed applications with the assistance of laboratory personnel, interviewed applicants, and hired qualified individuals to fill these positions during the first year. This includes a Clinical Coordinator and Research Assistants. We will move forward with timely hiring of additional qualified study support staff in the next year.

We have found a replacement after the unexpected passing of Dr. Thomas TenHave – a consultant biostatistician from the University of Pennsylvania named on the grant application. A decision was made to hire a Master’s level data management and biostatistics staff member at a 40% effort on the project to provide on-site assistance at USUHS. Given that no study data has been collected to date, we do not expect requiring advanced biostatistics support until Years 4 and 5 of the study. We will continue to consider suitable candidates to assist us with complex analytic procedures upon the completion of the study.

4. Developed study forms, database/randomization, risk management guide, and regulatory binders (Q 1-2)

Study forms, risk management guide, and regulatory binders

The research team developed the consenting and assessment guides based upon our experience implementing the pilot trials. Standard Operating Procedure (SOP) guides are being written for both consenting participants into the study and assessment to ensure adherence to study protocol. The SOP outlines study procedures, recommendations for working with this population, risk management procedures, adverse event reporting guidelines, and general information about the inpatient unit at WRNMMC. This includes making changes to our recruitment procedures based on several conversations with the WRNMMC inpatient psychiatry staff about the most effective ways to learn about and approach potential participants.

The research team developed and implemented a risk management protocol that defines imminent risk and details proper procedures when imminent risk is encountered both on the inpatient unit and during follow-ups. Information was gathered from the pilot trials that are currently in production.

Database/Randomization

We began collaboration with KAI to develop the study database, randomization procedures, and electronic study forms. Eight forms were provided by USUHS for database development of which KAI created seven electronic case report forms (eCRFs) in the SmartStudy™© database. KAI sent USUHS a Client Approval Packet including an approval form, the eCRF screens, and the edit specs on January 30th, 2012. Further revisions to the screens and edits are expected after the USUHS study team has an opportunity to review.

5. Prepared comprehensive baseline and follow-up assessment guide and training procedures (Q 1-2)

Comprehensive baseline and follow up assessment guides are in development based on the information gleaned from the pilot trials. Several conference calls were held with Dr. Goldston in order to discuss follow-up assessment procedures and ideas for decreasing attrition during the time of follow-up. Dr. Goldston has extensive experience in the conduct of longitudinal studies and he has recently had the opportunity to consult with several colleagues at the VA to learn more about the challenges associated with research follow-ups with a Military or Veteran sample. We discussed current retention rates for the pilot PACT trial and ways in which our

multi-site study retention could be maintained at the same or enhanced level. Meeting minutes were documented. We are using the information from the pilot trials to inform and develop assessment guides and training procedures. Training guidelines have been developed for baseline and follow-up assessment procedures, which have been informed by the pilot trials and conversations with Dr. Goldston and study research personnel.

6. Began preparing comprehensive treatment guide, case management, and training procedures (Q 1-3)

Comprehensive Treatment Guide

The PI and key study personnel at USUHS attended 1-2 meetings weekly for the purposes of finalizing the study treatment. The research team continues to revise the treatment protocol based upon our experiences thus far working with participants in the study as well as our experience working with participants in similar studies. In addition, we are making changes based upon the latest outcome data in the suicide prevention literature. The PI has continued to gain knowledge about various cognitive behavioral interventions for the treatment of suicidal individuals as well as evidence based inpatient treatment strategies. The research in this area has consisted of reading scientific literature, consulting with national and international subject matter experts, as well as informal communication with patients and providers about perceived treatment needs and gaps in inpatient care for individuals following a suicide attempt. The PI has participated as a member of the Defense Health Board's Task Force on the Prevention for Suicide by Members of the Armed Forces, the North Atlantic Treaty Organization's working group on military suicide, the Tragedy Assistance Program for Survivors Conference for Military Survivors, the DoD/VA clinical practice guidelines group on suicide prevention, and the DoD Suicide Prevention and Risk Reduction committee suicide nomenclature workgroup. All these activities, in addition to participation in national and international suicide meetings, have been instrumental in the scientific conceptualization, planning, and implementation associated with this clinical trial.

Case Management

The case management guide is currently in progress.

Training Procedures

Training guidelines have been developed for the following:

- Consenting participants
- Delivering the treatment

7. Did not prepare final version of adherence rating forms (Q 1-3)

We plan to consult with several collaborators on the study about the adherence rating form. The development of the adherence rating form is in progress and we plan to finalize this task within the next year.

8. Conducted training seminars for study assessment and treatment procedures (Q 3-4)

Two 2-hour training sessions were offered via phone/internet on TBI and the administration of the Ohio State University TBI Identification Method by Dr. Lisa Brenner from the Denver VA. Research assistants have been trained on pilot trials procedures and assessment administration is continually reviewed.

9. Did not setup Year 1 annual meeting for study collaborators (Q 3-4)

We have been in contact with each PI for the study and have planned to schedule an annual meeting in Year 2 after data collection has begun.

10. Did not setup Data Safety Monitoring Board (DSMB) and Year 1 DSMB annual meeting (Q 3-4)

We will solidify members for this group during the next quarter.

11. Prepared and submitted all applicable quarterly and annual reports (Q 1-4)

All quarterly and annual reports were submitted to the sponsor.

Additional tasks completed during Year 1, which were not specifically noted on the Statement of Work originally submitted with the grant application, are as follows:

- ✓ *Letter of Support for Access to DoD Population Based Data*
A letter of support was obtained on May 24, 2011 from the Armed Forces Health Surveillance Center (AFHSC) to allow access to the Defense Medical Surveillance System (DMSS) database, which will provide additional follow-up data on study participants.
- ✓ *Preparation of Cooperative Research and Development Agreement (CRADA)*
The WRNMMC IRB informed us that the previously submitted CRADA before the BRAC is now null and void. We will be following the guidance of the WRNMMC IRB to complete the new procedures required for the processing and approval of the CRADA.
- ✓ *Registration of Randomized Controlled Trial in ClinicalTrials.Gov*
On May 20, 2011, the information for the planned study was submitted to ClinicalTrials.Gov. The study is now registered on this system.
- ✓ *Contacted NIH to Request a Certificate of Confidentiality*
Based on a consultation with Ms. Olga Boikess at the National Institutes of Health (NIH), it was determined that we can submit our formal request for a certificate of confidentiality once the WRNMMC IRB approval has been obtained. Specific language to include in the study consent form was obtained.
- ✓ *Setup Study Related Email Address*
We requested a specific email address to be setup for the PACT study. Participants will receive email reminder notifications from this email address. The study participants will not be able to use this address to reply to messages sent to them.

- ✓ *Recruited Medical Monitor for Randomized Controlled Trial*
Given current work obligations at WRNMMC and the reluctance of most to avoid responsibilities on a suicide prevention trial, it was a challenging task to find a suitable medical monitor. Russell B. Carr, M.D. CDR MC USN, Psychiatrist, Service Chief, Adult Outpatient Behavioral Health Clinic, WRNMMC has kindly agreed to serve in this capacity for this study.

KAI Accomplishments:

KAI began working on the study database/randomization procedures, study data files, in addition to developing and maintaining a secure website to be accessed by study participants at the time of their follow-up assessments. Weekly conference calls were scheduled with KAI, Inc. to review study related tasks and problem solve challenges.

Protocol – KAI conducted a thorough review of the study protocol and provided feedback to the study team on two separate versions of the document. Additionally, KAI reviewed and provided comments on the following protocol sections as requested: Confidentiality Protection, HIPAA Authorization, and Randomization.

Safety Reporting – KAI reviewed the various Adverse Event (AE) and Serious Adverse Event (SAE) reporting documents provided by USUHS in an effort to devise a Safety Reporting Flow that would meet the needs of all the regulatory oversight entities. The flow was provided to USUHS prior to our group meeting on November 1, 2011. Further revisions are expected after the study team clarifies some potential rule changes to the safety reporting process.

Other Study Documents- KAI provided a sample screening log and an AE form as templates for forms that can be implemented in this study. In addition, suggested language for following up on AEs and documenting the consent process in the source was provided.

Team Meetings – KAI hosted an in-house meeting with USUHS on September 26, 2011 to discuss the status of the project and next steps. A second meeting took place on November 1, 2011. In addition, KAI and USUHS scheduled weekly teleconferences for Friday mornings at 1030 which commenced on November 18th. KAI drafts the meeting agendas and minutes for each weekly teleconference.

Project Management – Celeste Crouse, the KAI project manager performed the following duties: served as the first line of contact for USUHS, supervised the entire KAI study team, ensured that all deliverables to date were provided on time and of the highest quality and oversaw the execution of multiple authorization to proceed letters and ultimately the contract. The contract was officially signed on October 27, 2011.

Database Development – Eight forms were provided by USUHS for database development of which KAI created seven electronic case report forms (eCRFs) in the SmartStudy™© database. KAI sent USUHS a Client Approval Packet including an approval form, the eCRF screens, and the edit specs on January 30th, 2012. Further revisions to the screens and edits are expected after the USUHS study team has an opportunity to review.

Key Research Accomplishments

- Registration on ClinicalTrials.Gov
- Construction of Study Database & Electronic Entry Forms
- Hiring and Training of Study Staff
- Submission of the IRB Master Protocol to WRNMMC IRB
- Development of Study Consenting Procedures
- Final Selection of Study Assessment Instruments
- Preparation of Preliminary Version of Risk Assessment Guide
- Weekly Training and Supervision on Treatment Delivery
- Dissemination of Clinically Relevant Information in National & International Meetings
- Letter of Support from Armed Forces Surveillance Health Center
- Recruitment of Medical Monitor

Reportable Outcomes

Publications – Written Prior to Receipt of Funding, Yet Relevant to Current Study

Ghahramanlou-Holloway, M., Cox, D., & Greene, F. (2011). Post-admission cognitive therapy: A brief intervention for psychiatric inpatients admitted after a suicide attempt. Cognitive and Behavioral Practice. Epub ahead of print. doi: 10.1016/j.cbpra.2010.11.006

Dennis, J., **Ghahramanlou-Holloway, M.,** Cox, D., & Brown, G. (2011). A guide for the assessment and treatment of suicidal patients with traumatic brain injuries. Journal of Head Trauma Rehabilitation, 26, 244-256.

Presentations

Ghahramanlou-Holloway, M. (2011, February). Post Admission Cognitive Therapy (PACT) for the inpatient treatment of military personnel with suicidal behaviors: A multi-site randomized controlled trial. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Frederick, MD.

Ghahramanlou-Holloway, M. (2011, March). Evidence-based psychotherapy for suicide prevention: Practical tips from cognitive therapy. Invited presentation at the Annual Department of Defense and Veterans Administration Suicide Prevention Conference, Boston, MA.

Ghahramanlou-Holloway, M. (2011, March). Combat related trauma and suicide: Concepts of therapy. Invited symposium presentation with David Jobes and David Rudd at the 6th Aeschi Conference, Aeschi, Switzerland.

Szeto, E., Cox, D. W., Lou, K., Fritz, E., Engel, C., Bradley, J., Grammer, G., Wynn, G., & **Ghahramanlou-Holloway, M.** (2011, March). Gender differences on childhood and adulthood traumas: Inpatients admitted to a military psychiatric unit for suicide-related thoughts and behaviors. Poster presented at the Annual Department of Defense and Veterans Administration Suicide Prevention Conference, Boston, MA.

Ghahramanlou-Holloway, M. (2011, May). Evidence-informed approaches for the assessment and treatment of suicide-related ideation and behaviors. Invited 2 day training workshop provided to mental health providers in Denmark, Psychiatric Center, Copenhagen, Denmark.

Ghahramanlou-Holloway, M. (2011, July). Practical strategies for the assessment and management of suicidal patients. Invited presentation at the Malcolm Grow Medical Center, Andrews Air Force Base, MD.

Ghahramanlou-Holloway, M. (2011, December). *Protecting our volunteers and our nation: The ethical challenges of military research*. PRIM&R Advancing Ethical Research Conference, National Harbor, MD.

Conclusion

There are no study findings to report at the present time. The first year has heavily focused on obtaining appropriate regulatory approvals, developing study measures, hiring study personnel, preparing the study assessment battery, communicating with sites about study setup, the creation of the study master database, and development of the IRB Master Protocol. We expect to initiate study recruitment at the end of Year 2 upon the completion of data collection for the PACT pilot trials.

The early study conclusions are that at least 12-18 months need to be devoted to obtaining regulatory approvals for research pertaining to suicidal individuals receiving treatment in a military and VA settings. Institutional changes such as the Base Realignment and Closure can have significant impact on the conduct of research and associated timelines.

In summary, this study is responsive to the critical mental health care needs of military service members and beneficiaries by providing a targeted cognitive behavioral intervention for suicide ideation and behavior severe enough to warrant psychiatric hospitalization. The ultimate goal of the treatment is to prevent suicide and associated risk factors within a high risk group of the Armed Forces. Without adequate treatment, severe suicide ideation and attempt behavior may result in costly utilization of military, VA, and civilian health and social services, a decrease in operational readiness and morale, human suffering, and eventual death.

Furthermore, this study is aligned with several critical research areas recognized by the US Research and Materiel Command: (1) reduction of the impact of mental disorders for the Armed Forces; (2) development of strategies to enhance mental health and well-being throughout service members' careers; (3) validation of effective psychotherapy interventions; (4) targeted evidence-based risk reduction methods for suicide behavior; (5) development of valid treatment-related outcome measures and tracking systems; (6) reduction of barriers to care and appropriate linkage to healthcare services; and (7) special considerations for sub-populations with unique needs – for instance, those with combat trauma and/or Traumatic Brain Injury (TBI).

References

None.

Appendices

1. Appendix A – Presentation Slides

Ghahramanlou-Holloway, M. (2011, December). *Protecting our volunteers and our nation: The ethical challenges of military research*. PRIM&R Advancing Ethical Research Conference, National Harbor, MD.

PANEL III
**Protecting Our Volunteers and Our Nation:
The Ethical Challenges of Military Research**

Marjan G. Holloway, Ph.D.

Associate Professor, Clinical & Medical Psychology, Psychiatry
PRIM&R Advancing Ethical Research Conference
December 2, 2011
National Harbor, Maryland

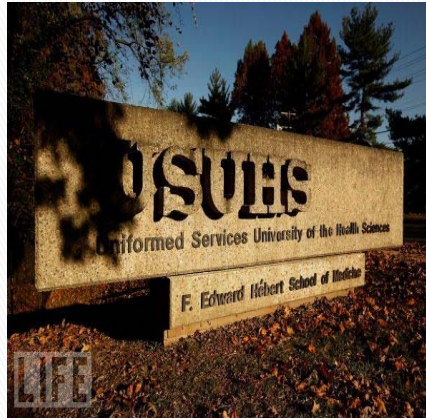


UNIFORMED SERVICES UNIVERSITY
of the Health Sciences

Presentation Outline

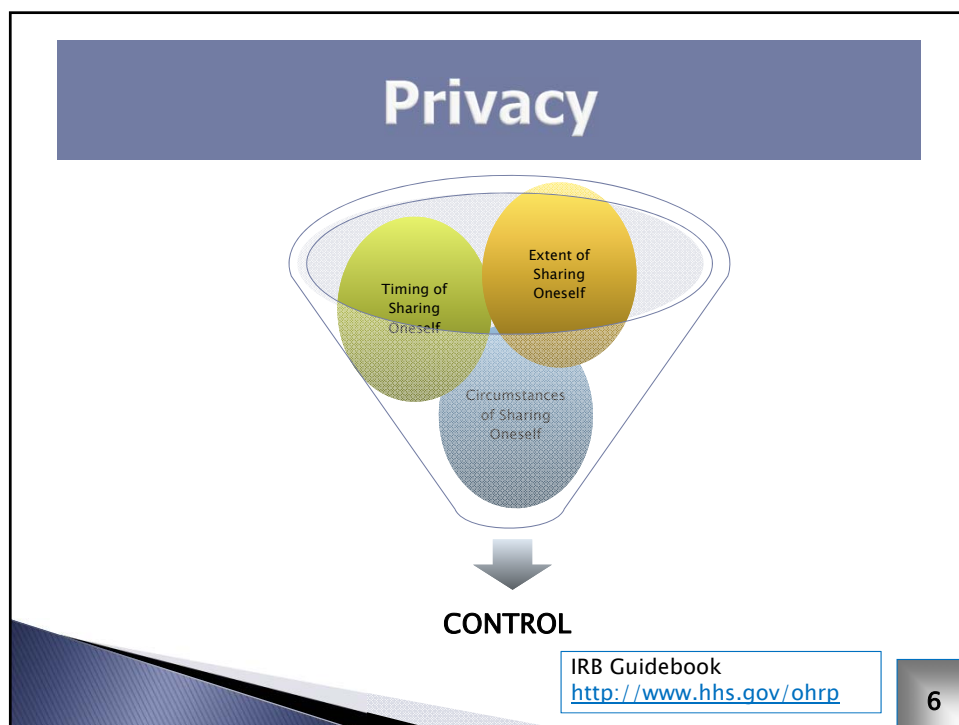
- ❖ Brief Overview of Suicide Prevention Research
- ❖ Privacy
- ❖ Confidentiality
- ❖ Safety and Risk Management

Laboratory for the Treatment of Suicide-Related Ideation and Behavior



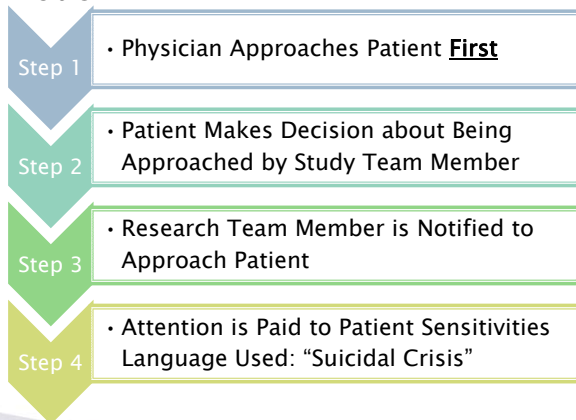
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	Trial 1	Trial 2	Trial 3	Trial 4
Number of Participants	N = 24	N = 64	N = 218	N = 189
Funding Source and Amount	National Alliance for Research on Schizophrenia and Depression \$60,000	Congressionally Directed Medical Research Program \$457,609	United States Department of Defense \$6,000,000	United States Department of Defense \$2,893,708
Inclusion Criteria	Inpatients Suicide Attempt	Inpatients Suicide Attempt AND Trauma	Inpatients Suicide Attempt Past OR Current	Inpatients Suicide Attempt OR Suicide Ideation
Intervention	Post Admission Cognitive Therapy (PACT)	Post Admission Cognitive Therapy (PACT)	Post Admission Cognitive Therapy (PACT)	Safety Planning
Sites	Walter Reed National Military Medical Center Ft. Belvoir Naval Medical Center Portsmouth			



Maximizing Privacy

❖ Respecting Patient's Privacy During the Time of Hospitalization

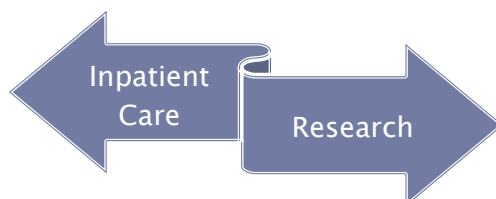


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Maximizing Privacy

❖ Setting Clear Boundaries for Inpatient Care versus Research

- Medical Chart Documentation Practices
- Authorization to Release Information Form



CONFIDENTIALITY

Confidentiality

Assessor/Therapist

Information Disclosed

Participant

IRB Guidebook
<http://www.hhs.gov/ohrp>

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Maximizing Confidentiality

- ❖ Preventing Accidental Disclosures

- No Assessment of Personality Disorders
- Evaluation of Personality Beliefs Instead

- ❖ Certificate of Confidentiality

- Limits Explained at Time of Consent

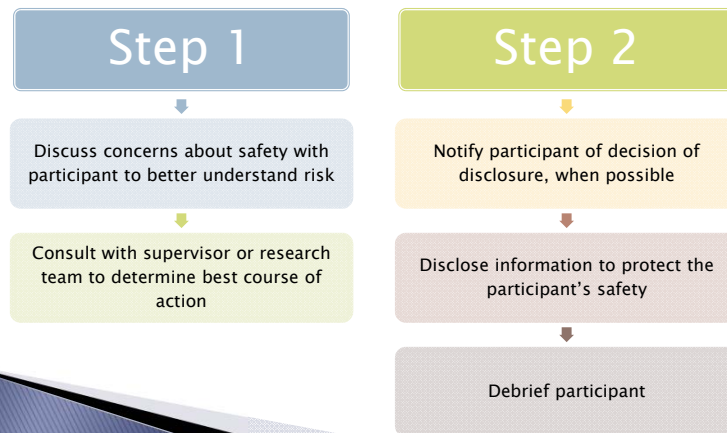


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Safety Risk Management

Maximizing Safety

❖ Communication of Risk & Disclosure



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Maximizing Safety

❖ Individualized Risk Profile Sheet

- Unique Risk & Protective Factors
- Access to Lethal Means
- Location & Resources
- Has Anything Changed Since We Last Talked?

❖ Data Safety Monitoring Board

- Review Study Data at Frequent Intervals
- At Least 1 Military Chaplain, Survivor, & Provider

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Summary

- ❖ Protecting Suicidal Service Members from Potential Negative Military Career-Related Implications
- ❖ Protecting Suicidal Service Members from Unintended Consequences such as Accidental Disclosure
- ❖ Protecting Suicidal Service Members from Harm to Self and/or Others

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